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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,852	06/27/2005	Kenji Okajima	OKAJIMA1	2332

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EXAMINER

AEDER, SEAN E

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

14

Office Action Summary	Application No. 10/540,852	Applicant(s) OKAJIMA ET AL.	
	Examiner Sean E. Aeder, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/13/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Claims 1-6 are pending.

Claims 3-6 have been amended by Applicant.

Claims 1-6 are currently under consideration.

Claim Objections

Claims 1-6 are objected to for reciting: "...medicament for improving prognostic survival in therapy of malignant tumor". There appears to be a word, such as "a", missing before "malignant". Proper correction is required.

Claim 2 is objected to for reciting: "...wherein said tumor is malignant tumor in hematopoietic organs". There appear to be typographical and/or grammatical errors. It is suspected Applicant intended claim 2 to recite: "...wherein said tumor is a malignant tumor in a hematopoietic organs". Proper correction is required.

Claims 4 and 5 are objected to for reciting: "...wherein said therapy of malignant tumor is chemotherapy". There appears to be a word, such as "said", missing before "malignant". Proper correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rejected as vague and indefinite for reciting the term "DIC". The use of an acronym renders the claim indefinite because the same acronym can have different meanings to different people. For example, post-filing teachings of Lash (Chemico-Biological Interactions, 2006, 163:54-67) describe use the acronym "DIC" to describe "dicarboxylate carrier" (see page 54, in particular). Amending the claims to specifically and uniquely identify "DIC" as "disseminated intravascular coagulation" can obviate the rejection (see page 4 line 8, in particular).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogata et al (US Patent 5,831,025).

Claim 1 is drawn to a medicament for improving prognostic survival in therapy of malignant tumor comprising as a main active ingredient Activated Protein C. Claim 2 is drawn to the medicament of claim 1, wherein said malignant tumor is a malignant tumor in hematopoietic organs. Claim 3 is drawn to the medicament of claim 1, wherein said

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malignant tumor is accompanied by DIC. Claim 4 is drawn to the medicament of claim 1, wherein said therapy of malignant tumor is chemotherapy. Claim 5 is drawn to the medicament of claim 4, wherein said therapy of malignant tumor is chemotherapy and said medicament may reduce thrombus formation induced by chemotherapeutics.

Claim 6 is drawn to the medicament of claim 1, wherein said medicament exhibits efficacy at a dose of 50 units/kg to 3000 units/kg. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Recitation of statements describing the claimed product as a medicament intended to treat a condition are not given patentable weight and are not limitations to the claims. Therefore, claims 1-6 are drawn to any product having Activated Protein C as the main active ingredient.

Ogata teaches purified Activated Protein C and a process for preparing Activated Protein C (see claims 1-11, in particular).

Claims 1-6 are further rejected under 35 U.S.C. 102(b) as being anticipated by Walker (The Journal of Biological Chemistry, 6/80, 255(12):5521-5524).

Claims 1-6 are described above.

Walker teaches purified Activated Protein C and a process for preparing Activated Protein C (see paragraph bridging page 5521-5522, in particular).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 7-9 of U.S. Patent No. 5,831,025. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3 and 7-9 of U.S. Patent No. 5,831,025 are drawn to species of instant claims 1-6. Recitation of an intended use does not distinguish the instant claims from 3 and 7-9 of U.S. Patent No. 5,831,025.

Summary

No claim is allowed.


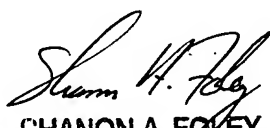
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA



SHANON A. FOLEY
SUPERVISORY PATENT EXAMINER